INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Laboratory Services

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Revision History

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of October 1, 2015 Published: February 25, 2016	New document	FSSA and HPE
1.1	Policies and procedures as of April 1, 2016 Published: October 27, 2016	Scheduled update	FSSA and HPE
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3.0	Policies and procedures as of May 1, 2018 Published: August 14, 2018	Scheduled update	FSSA and DXC
4.0	Policies and procedures as of July 1, 2019 Published: November 21, 2019	Scheduled update	FSSA and DXC
5.0	Policies and procedures as of June 1, 2020 Published: August 27, 2020	Scheduled update • Edited text as needed for clarity • Added billing information for comprehensive environmental lead investigation in the *Lead Testing* section	FSSA and DXC

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*Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the **fee-for-service (FFS)** delivery system. For information about services provided through the **managed care** delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect, or Hoosier Healthwise services – providers must contact the member's managed care entity (MCE) or refer to the MCE provider manual. MCE contact information is included in the IHCP Quick Reference Guide at in.gov/medicaid/providers.*

For updates to information in this module, see IHCP Banner Pages and Bulletins at in.gov/medicaid/providers.

Introduction

The Indiana Health Coverage Programs (IHCP) defines a *clinical laboratory* as a place where materials derived from the human body are tested, measured, or examined to provide information on diagnosis, monitoring, prevention, or treatment of disease or for information about impairment or assessment of health. IHCP reimbursement is available for most clinical diagnostic laboratory procedures performed in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients. Laboratory procedures are subject to the rules and regulations of the Clinical Laboratory Improvement Amendments (CLIA).

To be eligible for IHCP reimbursement, a laboratory service must be ordered in writing by a physician or other practitioner authorized to do so under state law, and the order must include a condition-related diagnosis that necessitates the laboratory services.

Clinical Laboratory Improvement Amendment Regulations

For IHCP reimbursement of laboratory services falling under CLIA regulations, the rendering provider must obtain a CLIA number and have a valid copy of the CLIA certificate on file with the IHCP provider enrollment contractor. The IHCP reimburses these providers only for lab codes allowed by the certificate.

CLIA certification types are as follows:

- Certificate of Waiver – This certificate is issued to a laboratory to perform only waived tests.
- Certificate for Provider-Performed Microscopy (PPM) Procedures – This certificate is issued to a laboratory in which a physician, midlevel practitioner, or dentist performs no test other than the PPM procedures. This certificate permits the laboratory to also perform waived tests.
- Certificate of Registration – This certificate is issued to a laboratory that enables the entity to conduct moderate or highly complex laboratory testing (or both) until the entity is determined by survey to be in compliance with the CLIA regulations.
- Certificate of Compliance – This certificate is issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.
- Certificate of Accreditation – This certificate is issued to a laboratory on the basis of the laboratory's accreditation by an organization approved by the Centers for Medicare & Medicaid Services (CMS).

For information about the procedures that are eligible for reimbursement under specific CLIA certificates, go to the CMS *CLIA* page at cms.gov and select **Categorization of Tests**.

The CLIA program is intended to ensure that providers performing laboratory procedures do so in accordance with federal regulations. For more information about CLIA, contact the Indiana State

Department of Health (ISDH). See the *Clinical Laboratory (CLIA) Licensing and Certification Program* web page at in.gov/isdh for contact information.

Hospital Outpatient Defined for Laboratory Services

The IHCP defines *hospital outpatient* as a member whom the hospital has not admitted as an inpatient but who is registered in hospital records as an outpatient and receives services directly from the hospital. If personnel not employed by the hospital take a tissue sample, blood sample, or specimen and send it to the hospital for tests, the IHCP classifies the tests as *nonpatient* (rather than outpatient) hospital services, because the patient did not directly receive services from the hospital.

Independent Diagnostic Testing Facilities

An independent diagnostic testing facility (IDTF) is a diagnostic testing facility (entity) that is independent of a physician's office or hospital (that is, it is not owned by a hospital, individual physician, or physician group). An IDTF furnishes diagnostic tests and does not use test results to directly treat patients. IDTFs are distinguished from facilities that provide similar services by their ownership structure and the types of services they perform. IDTFs must be enrolled in Medicare before enrolling in the IHCP.

Example of non-IDTF: A radiologist-owned or hospital-owned office that bills for professional interpretations and rarely bills for purchased interpretations or technical components only of diagnostic tests is *not* an IDTF.

An IDTF must employ one or more supervisory physicians who are proficient in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. A physician group practice cannot be considered a supervisory physician. In accordance with *Code of Federal Regulations 42 CFR 410.33 (b)(2),* Medicare IDTFs have discretion in determining the qualifications required of a supervisory physician if the physician is not certified in a medical specialty.

IDTF services are billed with place-of-service (POS) code 81 – *Independent laboratory* on a professional claim (*CMS-1500* claim form, Provider Healthcare Portal [Portal] professional claim, or 837P electronic transaction).

Reimbursement Methodology for Laboratory Services

Most clinical diagnostic laboratory procedures performed in a physician's office, by an independent laboratory, or by a hospital laboratory for outpatients are reimbursed at the rate on the applicable IHCP Fee Schedule (professional or outpatient) or at the submitted charge, whichever is lower. (The IHCP Fee Schedules are accessible from the *IHCP Fee Schedules* page at in.gov/medicaid/providers.)

For laboratory procedures on the Medicare Physician Fee Schedule that do not have relative value units (RVUs), IHCP reimbursement is based on the Medicare Clinical Laboratory Fee Schedule or manual pricing methodology, if a rate has not yet been established by Medicare.

Some procedures do not have RVUs on the Medicare Physician Fee Schedule because the procedure meets one of the following criteria:

- Associated with special restrictions
- Carrier-priced
- Excluded from the definition of physician services
- Excluded from the Medicare Physician Fee Schedule
- Noncovered by Medicare
- Not valid for Medicare

For laboratory procedures not covered by the Medicare Physician Fee Schedule as not meeting the definition of physician-provided services, the IHCP reimburses from the Medicare Clinical Laboratory Fee Schedule. For codes for which Medicare has not yet established a specific rate in the Medicare Physician Fee Schedule or the Medicare Clinical Laboratory Fee Schedule, the IHCP reimburses through manual pricing until Medicare assigns a rate.

Pursuant to Section *1903(i)(7)* of the *Social Security Act*, Medicaid reimbursement for individual clinical laboratory procedures cannot exceed the Medicare rate of reimbursement. In accordance with the clinical laboratory reimbursement methodology set out in *Indiana Administrative Code 405 IAC 5-18-1* and in the approved Medicaid State Plan, the IHCP adopts the Medicare rates for any clinical laboratory procedure code for which the IHCP's current reimbursement rate exceeds the Medicare rate. This analysis is performed typically at the beginning of each calendar year; thus, any rate changes are effective for dates of service on or after January 1 of the current year.

> *Note: Outpatient laboratory services, defined as the procedure codes listed on the Medicare Clinical Laboratory Fee Schedule, are not eligible for Hospital Assessment Fee (HAF) adjustments. See the Hospital Assessment Fee module for more information about the HAF program.*

Billing Procedures for Laboratory Services

When billing laboratory services, providers should use the pathology and laboratory guidelines noted in the Current Procedural Terminology (CPT®[1]) and Healthcare Common Procedure Coding System (HCPCS) codes. Clinical diagnostic laboratory services include all laboratory tests listed in CPT codes 80047 through 89331, as well as some G, P, and Q codes listed in the HCPCS Level II Code book.

Laboratory services must be ordered in writing by a physician or other practitioner authorized to do so under state law. Laboratories performing the services must bill the IHCP (or the appropriate managed care entity) directly, unless otherwise approved.

> *Note: Regulations require that the **laboratory analyzing the specimen** submit the charge to the IHCP. It is not appropriate for a **physician** to bill using **modifier 90 – Reference (outside) laboratory** for a laboratory service that was analyzed by an outside laboratory.*

Providers may submit only one claim when providing multiple laboratory services. If the provider administers the procedure to a member more than one time in the same day, the provider should bill it as only one line item, with an indication of the number of units of service given that day.

Hospitals must bill laboratory services on an institutional claim (*UB-04* claim form, Portal institutional claim, or 837I electronic transaction) using the most appropriate HCPCS or CPT code. Revenue codes billed without the appropriate HCPCS or CPT procedure code are denied.

Providers must bill the professional component of a laboratory service performed in an outpatient hospital setting on the professional claim (*CMS-1500* claim form, Portal professional claim, or 837P electronic transaction) with the appropriate HCPCS or CPT code and modifier **26** – *Professional component*.

See the *Claim Submission and Processing* module for general billing instructions.

[1] *CPT copyright 2020 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.*

> *Note: Hospice providers must not include costs for services such as laboratory and x-rays with the attending physician's billed charges. The daily hospice care rates that the IHCP pays include these costs, which are expressly the responsibility of the hospice provider. However, if an IHCP hospice member requires laboratory services* ***not related to the terminal illness****, the hospice provider is not responsible for these laboratory services. The IHCP allows for separate reimbursement of non-hospice-related laboratory treatment in these circumstances. IHCP providers billing for the treatment of nonterminal conditions are reminded that they are responsible for obtaining IHCP prior authorization (PA) for any nonhospice services that require PA.*

Billing for Professional and Technical Components

Some clinical diagnostic laboratory procedures have both professional and technical components of service. A physician typically performs the professional component of the lab procedure. The IHCP reimburses the physician for the professional component when the physician bills the appropriate CPT lab code along with modifier 26 – *Professional component*.

When billing only the technical component of the procedure, providers should append modifier TC – *Technical component* to the appropriate CPT lab code. When billing for both professional and technical components of service, providers should use no modifiers.

Providers should bill the appropriate lab code only. The Medicare Physician Fee Schedule at cms.gov includes information about lab codes billed using these modifiers.

Multiple Component Rebundling

As part of the Multiple Component Rebundling enhanced code auditing, the IHCP applies component rebundling logic to physician and institutional claims. This claim-editing process identifies claims containing two or more procedure codes used to report individual components of a service when a single, more comprehensive procedure code exists that more accurately represents the service performed. During component rebundling, individual unbundled procedures will be denied.

Lab Panels

Organ- or disease-oriented lab panels were developed to allow for coding of a group of tests. Providers are expected to bill the lab panel when all the tests listed within each panel are performed on the same date of service. When one or more of the tests within the panel are not performed on the same date of service, providers may bill each test individually. Providers may not bill for a panel *and* all the individual tests listed within that panel on the same day. However, *other* tests performed in addition to those listed on the panel on the same date of service may be reported separately, in addition to the panel code. Providers must follow CPT coding guidelines when reporting multiple panels. For example, providers cannot report basic panel code 80048 with comprehensive panel code 80053 on the same date of service, because all the lab tests in 80048 are components of 80053.

Specimen Collection

The IHCP allows a minimal fee for separate charges made by physicians, independent laboratories, or hospital laboratories for drawing or collecting specimens. The IHCP covers these services only when the provider draws a blood sample through venipuncture or collects a urine sample by catheterization. Providers must itemize specimen collection fees when billing for them. The IHCP allows only one charge per day, per member for venipuncture. The IHCP allows a charge for catheterization for each patient encounter; it does not limit this service per day or per claim.

Handling and Conveyance

The IHCP reimburses for handling and conveyance of a specimen to a laboratory if services are billed by a physician, chiropractor, or podiatrist, in accordance with *405 IAC 5-18-2(c)*. The IHCP reimburses providers for no more than two conveyance fees (procedure code 99000) per member, per provider, on the same date of service. Providers can charge this fee only if the physician, chiropractor, or podiatrist has an expense involved in conveyance.

Consultative Pathology Services

The IHCP covers consultative pathology laboratory services if the following conditions are met:

- The member's attending physician requested the service in writing.
- The service relates to a test result that lies outside the clinically significant normal or expected range in view of the condition of the member.
- The service results in a written narrative report in the member's medical record.
- The service requires the exercise of medical judgment by the consulting physician.

Policies and Procedures for Specific Laboratory Services

The following sections include coverage, billing, and reimbursement information for various types of laboratory services. For information about laboratory services related to a specific type of provider, service, or program, see the appropriate module:

- For laboratory services related to renal dialysis, see the *Renal Dialysis Services* module.
- For genetic testing coverage and billing, see the *Genetic Testing* module.
- For newborn screening blood tests, see the *Inpatient Hospital Services* module.
- For prenatal laboratory services and cervical cancer screening, see the *Obstetrical and Gynecological Services* module.
- For laboratory services covered under the Family Planning Eligibility Program, see the *Family Planning Eligibility Program* module.

> *Note: To determine whether a specific laboratory code requires prior authorization, see the IHCP Fee Schedules, accessible from the IHCP Fee Schedules page at in.gov/medicaid/providers.*

HIV Testing

The IHCP covers routine laboratory testing for human immunodeficiency virus (HIV) when it is done to establish an HIV diagnosis. HIV testing is covered only in circumstances when a blood sample is drawn through venipuncture or when a urine sample is collected by catheterization. The IHCP does not cover oral HIV testing methods.

The United States Preventive Services Task Force (USPSTF) has found evidence that identification and treatment of HIV infection is associated with a markedly reduced risk for progression to acquired immune deficiency syndrome (AIDS), AIDS-related events, and death in individuals with immunologically advanced disease. Providers are encouraged to follow USPSTF guidelines.

Lead Testing

For lead testing in the office setting, the coverage and reimbursement rate for code 83655 includes tests administered using filter paper and handheld testing devices. Providers should bill using the appropriate procedure code and modifier combination:

- 83655 – *Lead, quantitative; blood*
- 83655 U1 – *Lead, using filter paper*
- 83655 U2 – *Lead, handheld testing device*

See the *Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)/HealthWatch* module for lead testing policies and procedures specific to EPSDT-eligible members.

> *Note: The IHCP covers comprehensive environmental lead investigation – both initial (T1029) and follow-up (T1029 TS) services – for IHCP members with a confirmed elevated blood lead level (EBLL). EBLL is defined by the Centers for Disease Control (CDC) as a blood level of 5 mcg/dL or higher.*
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> *The services must be billed by an IHCP-enrolled county health department (provider type 13, specialty 130). Providers must adhere to current ISDH guidelines per 410 IAC. Licensed risk assessors or lead inspectors, as defined in 410 IAC 29-1, are not recognized as IHCP billing providers. These entities must work with the appropriate health departments for services to be covered.*
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> *Services are limited to one unit, per member, per 12-month rolling calendar year. Prior authorization is not required for initial and follow-up comprehensive environmental lead investigation.*
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> *All comprehensive environmental lead investigation services are carved out of managed care, which means these services will be reimbursed through the fee-for-service (FFS) delivery system, including for members enrolled in managed care programs.*

Oncology (Colorectal) Screening

The IHCP covers CPT code 81528 – *Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result (Cologuard)*. Coverage is limited to once every 3 years for individuals ages 50 through 75.

Reimbursement and coverage information is included in the IHCP Fee Schedules (both outpatient and professional), accessible from the *IHCP Fee Schedules* page at in.gov/medicaid/providers.

Urine Drug Testing

The IHCP covers presumptive urine drug testing (UDT) and definitive UDT when medically necessary. In most situations, initial UDT can be performed with presumptive testing for commonly prescribed opioids and illicit drugs. The use of definitive testing should be based on the need to detect specific opioids that cannot be identified on presumptive UDTs or on the presence of unexpected UDT results. Providers should **not** test for substances for which results would not affect patient management. UDT is **not covered** for any of the following circumstances:

- Unnecessarily frequent drug testing without consideration for a specific drug's window of detection
- Testing for the same drug with both a blood or saliva test and a urine specimen simultaneously (multiple tests seeking the same outcome)
- Testing for legal intervention or employment

The IHCP requires PA for definitive UDT performed beyond the first 20 definitive tests per member per calendar year. PA is not required for presumptive UDT or for the first 20 definitive UDTs per member per calendar year. Providers should bill the appropriate CPT code for UDT as follows:

- Presumptive UDT: 80305–80307
- Definitive UDT: 80320–80377; G0480–G0483